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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,555	03/29/2005	Flemming Madsen	P70463USD	7874
13% 7590 08/01/2008 JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004				
EXAMINER				
BERMAN, SUSAN W				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/529,555

Applicant(s)

MADSEN ET AL.

Examiner

/Susan W. Berman/

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Response to Amendment

See the new matter rejection of claims under 35 USC 1st paragraph set forth herein below.

Declaration of Fleming Madsen

Dr. Madsen's arguments with respect to the phrase "and copolymers of", i.e., copolymers of the recited polymers, in claims 15-16 is unpersuasive. See the rejection set forth herein below for further discussion. A change in wording is suggested to express what is intended.

With respect to Dr Madsen's remarks about the disclosure of Hu et al, the remarks focus on the examples disclosed in Hu et al. However, the disclosure of Hu et al is not limited to the examples. Free radical thermal initiators and photoinitiators are taught for use alone or in combination, such as azo and peroxide compounds and phenyl ketone photoinitiators, thereby suggesting use of peroxy initiators [0047].

Dr Madsen's remarks about the disclosure of Sawhney et al also focus on the examples disclosed; however, the disclosure of Sawhney et al is not limited to the examples. Sawhney et al disclose persulfate initiators as redox initiators and also disclose that the hydrogel compositions can be cured by exposure to UV. As set forth in the rejection of record, applicant teaches that it was known in the art at the time of the instant invention that water-soluble persulfates decompose upon exposure to UV radiation. For instance, articles disclosing that photodecomposition of peroxydisulphates in aqueous medium and to photopolymerize methyl methacrylate was known prior to the instant invention are cited at pages 9-10 in the instant specification. Therefor, applicant's argument that there was no motivation to combine the teachings in the cited prior art and use persulfates as photoinitiators is unpersuasive.

While it is agreed that the two articles by Ikkai et al cited in the Declaration present use of persulfates to produce polymer gels in solution using UV irradiation, the disclosures do not negate the teachings of the cited art of record.

The data presented in the Declaration on pages 12-14 has been considered and found persuasive of unexpected results with respect to the instantly disclosed method compared with the disclosures of the prior art. However, the method claims 11-20 and 24 are not considered to be commensurate in scope with the showing provided. There is no evidence provided that the results relied upon can be obtained with crosslinking agents other than di- or higher multi-functional (meth)acrylates, such as PEG-DMA and equivalent (meth)acrylates disclosed on page 18, line 24, to page 19, line 6. It is also noted that the wt. % of crosslinker and function as co-catalyst are also critical, as disclosed on page 17, line 22, to page 18, line 9. The data is not considered to support patentability of claims 21-23 because there is no evidence to show that the composition as claimed provides unexpected results or that the product as claimed has significantly different properties from the prior art hydrogels, including hydrogels produced using initiators other than persulfates since the initiators are not expected to be incorporated into the products in the prior art or in the invention.

Response to Arguments

Applicant's arguments filed 5-14-2008 have been fully considered but they are not fully persuasive.

It is noted that newly submitted claim 24 is an independent claim reciting a process that differs from claim 11 in that the thickness of the sheet or coating is about 10 μm to about 200 μm .

Sawhney et al teach that persulfates, as well as peroxygen compounds such as hydrogen peroxide, are suitable initiators in a polymerization method analogous to the method disclosed by Hu et al. Applicant discloses in the "Background of the Invention" that it is known in the art that peroxides may be used as photoinitiators of vinyl polymerization, such as hydrogen peroxide, peroxydisulphate or peroxydiphosphate (page 5, lines 4-12). Applicant also teaches that peroxydisulphate is used equivalently to "persulphate" (page 5, lines 4-5). Applicant also admits that it is known in the art to enhance peroxide initiated polymerization by addition of soluble metal ions (page 6).

Sawhney et al clearly teach persulfates function as initiators. The instant claims are drawn to a method comprising preparing an aqueous solution containing a saturated hydrophilic polymer, a crosslinking agent and a water soluble peroxydisulphate and irradiating the solution. Irradiation of a solution comprising the same components disclosed in the prior art would be expected to result in crosslinking and in a crosslinked hydrogel product.

With respect to claims 21-22, the claim amendment reciting the concentration of the peroxydisulphate photoinitiator is considered to be within the ordinary skill in the art to determine the amount of initiator required for a desired result.

With respect to claim 23, drawn to a cross-linked hydrogel product by process, the hydrogels disclosed by Hu et al formed from a hydrophilic polymer and a crosslinking agent wherein the hydrogel is in the form of a coating or sheet having a thickness from about 200 μm

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to about 2 cm would be the same as the hydrogels instantly claimed or obvious variants. The reason is that the photoinitiator initiates cure but is not expected to be incorporated into the hydrogel product.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-20 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner has not found any description in the instant specification as originally filed of the following limitations added in the amendments filed 5-14-2008: with respect to claim 11, a thickness “between about 200 μm to about 2 cm”; with respect to claim 24, a thickness “between about 10 μm to about 200 μm ”. What is disclosed in the specification at page 13 is “thickness such as 10 μm to 2 cm”. No basis is found for the term “about” or for the division into the ranges 10 μm to 200 μm and 200 μm to 2 cm. The Examples disclose 5 mm as the thickness of the sheets.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what is meant by “copolymers of the foregoing” because the “foregoing” are polymers. What is meant by a copolymer of a polymer? Does applicant intend to claim block copolymers? Does applicant intend to claim copolymers of the monomers from which the polymers were obtained, such as copolymers of vinyl pyrrolidone or copolymers of methacrylic acid? It is suggested that the claim recite “polymers, copolymers and blends thereof of cellulose derivatives, saccharides, vinylpyrrolidone, vinyl alcohol, acrylic acid, methacrylic acid, ethylene glycol, vinyl ether or maleic anhydride”.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al [US 2001/0044482 A1] in view of Sawhney et al (5,844,016).

Hu et al disclose IPN compositions for forming hydrophilic hydrogel contact lenses comprising polymerizable monomers and crosslinking agents and a soluble hydrophilic IPN agent, such as polyvinylpyrrolidone, and a photoinitiator and/or a thermal initiator. The crosslinker is preferably polyethylene glycol dimethacrylate [0044]. Free radical thermal initiators and photoinitiators are taught for use alone or in combination, such as azo and peroxide

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compounds and phenyl ketone photoinitiators [0047]. Peroxydisulfate initiators are not mentioned.

Sawhney et al teach a polymer gel obtained by photopolymerization of acrylated PEG in the presence of a combination of chemical initiators and photochemical initiators. The chemical initiators disclosed include potassium persulfate, ammonium persulfate, peroxygen compounds such as hydrogen peroxide and redox catalyst with a transition metal (column 5, lines 38, to column 6, line 56). Sawhney et al teach that a very slow redox-catalysed polymerization can be speeded up by including metal ions and by stimulation of a photoinitiator in the solution (column 6, lines 46-52) See Examples 11, 12 and 22. Sawhney et al teach polymerization by irradiation of acrylated PEG in aqueous solution and in the presence of a photoinitiator, an organic peroxide, such as hydrogen peroxide, and a ferrous ion. Sawhney et al teach polymerizing monomers to form a surface coating that appears to be a graft polymerization on the surface, such as a tissue surface. Example 10 discloses a solution comprising polyethylene glycol 400 and an acrylated PEG crosslinking monomer.

It would have been obvious to one skilled in the art at the time of the invention to substitute the initiator system taught by Sawhney et al for the initiator system in the method disclosed by Hu et al. Hu et al provide motivation by teaching that peroxide initiators are useful. Sawhney et al provide motivation by teaching persulfates, as well as peroxygen compounds such as hydrogen peroxide, are suitable initiators in an analogous polymerization method. Sawhney et al also teach that a slow redox-catalysed polymerization can be speeded up by including metal ions and by stimulation of a photoinitiator in the solution in the presence of the metal ions. One skilled in the art at the time of the invention would have been motivated by a reasonable

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expectation of taking advantage of the benefits of providing an initiator comprising a photoinitiator, an organic peroxide and ferrous ions to speed up the polymerization, as taught by Sawhney et al. It would further have been obvious to one skilled in the art at the time of the invention to determine the wt. % photoinitiator required to obtain a desired product of a desired thickness and within a desired time, in the absence of evidence to the contrary.

With respect to claims 12 and 22, It would have been obvious to one skilled in the art at the time of the invention to employ a mixture of the IPN agents taught by Hu et al in the compositions taught by Hu et al. The reason is that Hu et al teach several different saturated polymeric IPN agents that provide the same function in the disclosed method.

With respect to claims 21-22, the claim amendment reciting the concentration of the peroxydisulphate photoinitiator is not considered to distinguish the instantly claimed composition from the teachings of the cited prior art. It is considered to be within the ordinary skill in the art to determine the amount of initiator required for a desired result. One skilled in the art at the time of the invention would have been motivated by a reasonable expectation of successfully gelling the compositions.

With respect to claim 23, drawn to a cross-linked hydrogel product by process, the hydrogels disclosed by Hu et al formed from a hydrophilic polymer and a crosslinking agent wherein the hydrogel is in the form of a coating or sheet having a thickness from about 200 μm to about 2 cm would be the same as the hydrogels instantly claimed or at least obvious variants thereof. The reason is that the photoinitiator initiates cure but is not expected to be incorporated into the hydrogel product.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Susan W. Berman/ whose telephone number is 571 272 1067. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SB
7/25/2008

/Susan W Berman/
Primary Examiner
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